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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/623,793
Filing Date: September 08, 2000
Appellant(s): VERKAART ET AL.

Conrad J. Clark
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/29/07 appealing from the Office action mailed 8/24/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is partially correct. Claims 1, 3, 5-7, and 15-19 stand rejected under 35 U.S.C 102 (e) as being anticipated by Esposito.

WITHDRAWN REJECTIONS The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the Examiner. Claims 4, and 8-10 are indicated as being allowable if rewritten in independent form including all limitations in the base claim and intervening claims.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,997,811	Esposito	12-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-7, and 15-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Esposito (USPN 5,997,811).

Esposito discloses a syringe and a syringe package sterile apparatus that comprises: a syringe for transferring non-sterile; a casing first part (50) and a second part (30; col. 4, lines 1-50) configured to receive a sterile syringe (20) containing a non-sterile fluid (col. 2, lines 4-9). The non-sterile fluid flows through the first part (50) and into the sterile syringe, which is in the sterile package. The first part (50, lap joint or luer connector, col. 2, lines 13-29) receives the barrel portion of the syringe and the second part (30) receives the plunger portion of syringe (see fig. 1). The first part (50) is a rigid tube and the second part (30) is flexible sheet (sheath, shape of a bag)(see fig. 1; col. 4, lines 1-12). The second part (30) creates a bellow when the user applies pressure to the plunger to draw fluid into the syringe. The sterile sheath of the sterile syringe package can be made of a radiation stable thermoplastic material or a breathable material sterilizable by gas or steam (col. 2, lines 24-28). It is noted that Esposito discloses the sheath may be made from a flexible material such as a thermoplastic material (col. 5, line 6, fig. 2, shows flexibility).

(10) Response to Argument

Appellant argues, "that Esposito does not teach the limitations recited in claim 1, namely a 2 part casing which is flexible and allows operation of the syringe while in the casing." Esposito discloses in a preferred embodiment of the present invention, a fluid can be introduced into the sterile syringe 20 encased in the syringe packaging 10.

Since the encased syringe 20 does not have a needle thereon for the above reasons, another syringe or other fluid source (not shown) can be employed to inject the fluid into the encased syringe 20 through the fitting member 50 of the syringe packaging 10 and the luer or needle fitting 22 of the syringe 20. Then, the syringe package 10 may be subjected to subsequent processing including transportation (col. 5, lines 37-47). Further claim 1 of Esposito discloses: sterilizing a syringe package, which package is adapted to receive and encase the syringe in a sterile manner **while permitting operation of the syringe**. This statement and the above paragraph specifically state that the syringe can be operated within the sterile enclosure, which enclosure is made from a flexible material such as a thermoplastic material (col. 5, line 6, fig. 2, shows flexibility).

Appellant argues, "It is again pointed out that Esposito does not show a two-part enclosure where a first part receives the barrel, the second part receives the plunger, and sterility is maintained when the first and second parts are connected. Thus, Esposito does not anticipate the claims, and the rejection under 35 USC 9102 cannot stand." Esposito discloses a syringe and a syringe package sterile apparatus that comprises: a syringe 20 for transferring non-sterile; a casing first part (50) and a second part (30; col. 4, lines 1-50) configured to receive a sterile syringe (20) containing a non-sterile fluid (col. 2, lines 4-9). The non-sterile fluid flows through the first part (50) and into the sterile syringe, which is in the sterile package. The first part (50, lap joint or luer connector, col. 2, lines 13-29) receives the barrel portion of the syringe and the second part (30) receives the plunger portion of syringe (see fig. 1).

With respect to the first part being readily detachable from the second part. Esposito discloses that the sterile sheath 30 can have a tear off portion 42 where the sheath can be torn open or peeled open by the user to deliver the sterile syringe 20 to the a sterile environment. The tear off portion 42 overlaps at least a portion of the sealing line 40. When being peeled open, the sealing line 40 breaks so that the first and second sheets 38a and 38b can depart from each other there along. Therefore the first part 50 is readily detachable from 38a and 38b because when the sheath is opened the first part 50 is still attached to the syringe.

Appellant argues, "Esposito does not disclose any structur whereby an operator can operate the syringe from the exterior of the sterile package by grasping and manipulating the plunger of the syringe." The Examiner has already shown that casing 10 is flexible plastic and is relatively then. A user would grasp the plunger through casing 10 and depress the plunger to expel liquids or pull the plunger to withdraw fluids within the syringe. Therefore, Exposito is structurally capable of performing the functions of the instant application.

The Examiner withdraws the rejection on claim 4 and 8-10 based upon the Appellants arguments.

Appellant argues with respect to claims 5,6 and 19, Esposito fails to disclose a flexible sheet. The Examiner points to col. 5, lines 53-56 where Espositio recites, "The sterile operator may grasp the sterile syringe and remove it from fitting member 50 without compromising the sterility of the syringe." This occurs while the syringe is in the

flexible thermoplastic 10 enclosure. Since a user is able to grasp the syringe through the thermoplastic enclosure 10, the enclosure is flexible.

Appellant argues with respect to claim 18, Esposito show no structure that includes gripping elements. The Examiner argues that the plunger is a gripping member when a user grasps the plunger through the thermoplastic enclosure 10.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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